IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, on behalf of itself and all others similarly situated	*	
Plaintiff,	*	Civil Action No. GLR-18-3560
v.	*	
ACTELION PHARMACEUTICALS Ltd.,	*	
Defendants.		

***

MEMORANDUM OPINION

THIS MATTER is before the Court on Plaintiff Government Employees Health Association's ("Government Employees") Motion to Certify Class (ECF No. 232), Government Employees' Motion to Exclude the Opinions of James W. Hughes, Ph.D and Sean Nicholson, Ph.D Related to Class Certification (ECF Nos. 238, 260), Defendants Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Janssen Research & Development, LLC's (collectively, "Actelion") Motion to Exclude the Opinions and Testimony of Meredith Rosenthal, Ph.D (ECF Nos. 234, 245), and Actelion's Motion to Exclude the Opinions and Testimony of Laura Craft (ECF Nos. 237, 246). The Motions are ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2023). For the reasons set forth below, the Court will grant Government Employees' Motion to Certify Class, grant in part and deny in part Government Employees' Motion to Exclude the Opinions of James W. Hughes and Sean Nicholson, and deny Actelion's Motions to Exclude the Opinions and Testimony of Meredith Rosenthal and Laura Craft.

I. BACKGROUND[1]

A. Factual Background

The Second Amended Complaint's facts are largely unchanged from the original Complaint, which the Court summarized in its September 30, 2019 Memorandum Opinion as follows:

> Actelion is a pharmaceutical company that produces and sells Tracleer, the brand name for the drug bosentan, which is used to treat pulmonary artery hypertension ("PAH"). (Pls.' Consol. Class Action Compl. & Demand for Jury Trial ["Am. Compl."] ¶ 1, ECF No. 34). PAH is a disorder in which elevated blood pressure causes narrowing of the arteries between the heart and lungs, restricting blood flow and causing extra strain on the heart. (Id.). PAH is relatively rare, affecting between 10,000 and 20,000 people in the United States, but it is chronic and potentially fatal. (Id.).
>
> Researchers at Hoffman-LaRoche Inc. ("Roche") discovered and developed bosentan in the 1990s. (Id. ¶ 92). In 1992, the co-inventors of bosentan submitted a patent application to the U.S. Patent and Trademark Office ("PTO"). (Id. ¶ 93). In 1994, the PTO issued the patent for bosentan (the "Patent") and assigned it to Roche. (Id. ¶ 94). In 1997, Roche assigned the Patent to Actelion—which was founded by a small group of former Roche scientists and managers—giving Actelion the exclusive right to develop, make, and sell products covered by the Patent. (Id. ¶ 97). Actelion has been the sole licensee of the Patent since 1997. (Id.).
>
> In 2000, Actelion sought approval from the U.S. Food and Drug Administration ("FDA") to sell tablets of bosentan under the tradename Tracleer for the treatment of PAH. (Id. ¶¶ 98–99). At the time, there were no approved oral treatments for PAH. (Id. ¶ 101). The FDA approved Tracleer for treatment of PAH on November 20, 2001. (Id. ¶ 107). In approving

[1] Unless otherwise noted, the Court takes the following facts from the Second Amended Complaint (ECF No. 74) and accepts them as true. See Erickson v. Pardus, 551 U.S. 89, 94 (2007).

Tracleer, the FDA granted Actelion two regulatory exclusivities: first, because Tracleer was a new chemical entity, Actelion would have regulatory exclusivity until November 20, 2006; and second, the FDA deemed Tracleer an "orphan drug," giving Actelion an additional two years of market exclusivity. (Id. ¶ 108). These regulatory exclusivities guaranteed that Actelion would not face competition to Tracleer from generics until November 20, 2008 at the earliest. (Id. ¶¶ 108, 117). Further, Actelion would have patent exclusivity over Tracleer until the Patent expired on November 20, 2005. (Id. ¶¶ 96, 109).

After receiving FDA approval, Actelion launched the Tracleer Access Program ("TAP"), which limited sales of Tracleer to purchasers who agreed to certain limitations on the use of the drug. (Id. ¶¶ 111, 124, 126). In 2009, the FDA approved a Risk Evaluation and Mitigation Strategy ("REMS") for Tracleer. (Id. ¶ 118). The REMS provided that "Tracleer is available only through a special restricted distribution program called [TAP]" and "Tracleer may be dispensed only to patients who are enrolled in and meet all conditions of [TAP]." (Id. ¶ 120). The REMS also explained that only prescribers and pharmacies registered with TAP may prescribe and distribute Tracleer. (Id. ¶ 121).

Beginning in 2009, various generic drug manufacturers—Zydus Pharmaceuticals (USA) Inc. ("Zydus") and its partner Cadila Healthcare Ltd. ("Cadila"), Apotex, Inc. ("Apotex"), Actavis, Inc. ("Actavis"), and Roxane Laboratories, Inc. ("Roxane") (collectively, the "Generics")—sought to purchase samples of Tracleer from Actelion's certified distributors and wholesalers in order to conduct bioequivalence testing, which is a prerequisite to FDA approval of the generic version of the brand-name drug. (See id. ¶¶ 42–52, 130, 138–58, 161–72). In their requests, the Generics indicated they would be willing to pay market price for Tracleer and comply with any limitations in Tracleer's TAP and REMS. (Id. ¶¶ 140, 143–44, 146, 150, 153, 162, 169). Nonetheless, Actelion and its certified distributors and wholesalers repeatedly denied the Generics' requests to purchase Tracleer. (Id. ¶¶ 138–39, 141, 152, 154–55, 157, 165–66). At the time, Actelion advanced two primary reasons for its refusal to sell Tracleer to the Generics: (1) Actelion sought to protect its intellectual property rights; and

(2) providing Tracleer to Generics would violate the REMS' distribution restrictions. (Id. ¶ 170; see also id. ¶¶ 152, 155, 157, 166). Without access to samples of Tracleer, the Generics were unable to conduct bioequivalence studies, and therefore could not seek approval of generic bosentan from the FDA. (See id. ¶ 167–68).

In September 2012, Actelion sued Apotex and Roxane in the U.S. District Court for the District of New Jersey, seeking a declaration that Actelion had no duty to supply Tracleer samples to prospective generic competitors and that doing so would be in violation of the REMS for Tracleer. (Id. ¶¶ 173–76). Apotex and Roxane filed counterclaims against Actelion in November 2012, alleging that Actelion's refusal to distribute samples of Tracleer for bioequivalence testing constituted an abuse of monopoly power in violation of federal and state antitrust laws and FDA regulations. (Id. ¶¶ 177–86). The same month, Actavis moved to intervene, complaining that Actelion refused to sell Tracleer in order to block or delay generic competition. (Id. ¶¶ 187–88).

On January 16, 2013, Actelion moved to dismiss Apotex, Roxane, and Actavis's counterclaims. (Id. ¶ 189). In May 2013, while Actelion's motion to dismiss was still pending, Apotex again requested Tracleer samples from Actelion, this time attaching a recent letter from the FDA approving the safety protocols used in Apotex's bioequivalence testing. (Id. ¶ 199). As it had done before, Actelion refused Apotex's request. (Id.). Zydus and Cadila intervened in the litigation on July 9, 2013 on the grounds that Actelion had also denied them access to Tracleer samples. (Id. ¶ 200).

The court denied Actelion's motion to dismiss on October 17, 2013. (Id. ¶ 206). On November 1, 2013, Actelion settled with Apotex on undisclosed terms, and Apotex dismissed its claims and counterclaims with prejudice. (Id. ¶ 212). Actelion settled with the remaining Generics on undisclosed terms in February 2014. (Id. ¶ 213).

The Patent expired on November 20, 2015, ending Actelion's legal exclusivity over bosentan. (Id. ¶¶ 1, 109). To date, there

> is no generic version of bosentan available on the market. (Id. ¶ 1).[2]

(Sept. 30, 2019 Mem. Op. at 2–5, ECF No. 50)[3].

Also factually relevant to the pending motions is the payment scheme for Tracleer. Typically, the drug distribution chain begins with manufacturers which sell the drug to wholesalers that then distribute the drug to pharmacies. The pharmacies then, through intermediaries including pharmacy benefit managers ("PBMs"), third-party administrators, and administrative services only providers, sell the drug to third-party payors ("TPPs," also known as end-payors). The TPPs, which generally are insurers or self-funded employers, then pass the drug on to the consumer. Here, because of the REMS program in place, the manufacturer, Actelion, skipped the wholesaler and distributed Tracleer directly to a limited number of specialty pharmacies. (Pls.' Mem. Supp. Mot. Class Certification ["Mot. Class Cert."] at 21, ECF No. 232-1). These specialty pharmacies then, through PBMs, sold these drugs to TPPs, which passed them on to consumers.

B. Procedural Background

Initial Plaintiff Mayor & City Council of Baltimore (the "City") filed its original Complaint against Actelion on November 19, 2018. (ECF No. 1).[4] Upon the City and Government Employees' unopposed Motion for Consolidation and Appointment of Interim Class Counsel, (ECF No. 32), this Court consolidated Government Employees

[2] There are now generic versions of bosentan on the market. (See Mot. Class Cert. at 11).

[3] Citations to the page numbers refer to the pagination assigned by the Court's Case Management/Electronic Case Files ("CM/ECF") system.

[4] The City has since voluntarily dismissed all of its claims against all defendants.

Health Association v. Actelion Pharmaceuticals, Ltd., et al., No. GLR-18-3571 (D.Md. filed Nov. 20, 2018) with the present case on January 18, 2019. (ECF No. 33). On January 25, 2019, the City and Government Employees filed a Consolidated Class Action Complaint and Demand for Jury Trial ("Amended Complaint") on behalf of themselves and similarly situated individuals in thirty states and U.S. territories.[5] (ECF No. 34). On September 30, 2019, the Court granted Actelion's Motion to Dismiss Plaintiffs' Amended Complaint for failure to state a claim. (ECF No. 50). The United States Court of Appeals for the Fourth Circuit reversed and remanded the case for further proceedings. (ECF No. 55). The City and Government Employees filed a Second Amended Complaint on July 8, 2021. (ECF No. 74). The forty-six count Second Amended Complaint alleges: unlawful refusals to deal and attempts to monopolize in violation of § 2 of the Sherman Act, 15 U.S.C. § 2 (2018) (Count 1); violations of various state antitrust laws[6] (Counts 2–26); and

[5] Government Employees defined the putative class as "[a]ll persons and entities" in Arizona, California, District of Columbia, Florida, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Virginia, West Virginia, and Wisconsin "who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, at any time during the period from November 20, 2015 through and until the anticompetitive effects of Defendants' challenged conduct cease . . . ." (Am. Compl. ¶¶ 285–86, ECF No. 34). This class definition remains unchanged in the Second Amended Complaint, as discussed below. (2d Am. Compl. ¶¶ 282–83, ECF No. 74).

[6] Specifically, Government Employees alleges violations of the: Arizona Uniform State Antitrust Act (Count 2) (2d Am. Compl. ¶¶ 308–15); District of Columbia Antitrust Act (Count 3) (Id. ¶¶ 316–21); Illinois Antitrust Act (Count 4) (Id. ¶¶ 322–27); Iowa Competition Law (Count 5) (Id. ¶¶ 328–32); Maine Antitrust Statute (Count 6) (Id. ¶¶ 333–38); Maryland Antitrust Statute (Count 7) (Id. ¶¶ 339–45); Massachusetts General Statutes (Count 8) (Id. ¶¶ 346–54); Michigan Antitrust Reform Act (Count 9) (Id. ¶¶ 355–60);

violations of various state consumer protections laws.[7] (Counts 27–46). (Tracleer Pls.' Am. Consol. Class Action Compl. & Demand for Jury Trial ["2d Am. Compl."] ¶¶ 292–655, ECF No. 74). Government Employees seek declaratory, injunctive, and equitable relief. (Id. at 79–130).

Minnesota Antitrust Law (Count 10) (Id. ¶¶ 361–66); Mississippi Antitrust Statute (Count 11) (Id. ¶¶ 367–74); Missouri Merchandising Practices Act (Count 12) (Id. ¶¶ 375–80); Nebraska Junkin Act (Count 13) (Id. ¶¶ 381–86); Nevada Unfair Trade Practices Act (Count 14) (Id. ¶¶ 387–95); New Hampshire Antitrust Statute (Count 15) (Id. ¶¶ 396–401); New Mexico Antitrust Act (Count 16) (Id. ¶¶ 402–07); New York General Business Law (Count 17) (Id. ¶¶ 408–13); North Carolina General Statutes (Count 18) (Id. ¶¶ 414–18); North Dakota Uniform State Antitrust Act (Count 19) (Id. ¶¶ 419–24); Oregon Antitrust Law (Count 20) (Id. ¶¶ 425–30); Puerto Rican Anti-Monopoly Act (Count 21) (Id. ¶¶ 431–35); Rhode Island Antitrust Act (Count 22) (Id. ¶¶ 436–40); South Dakota Antitrust Statute (Count 23) (Id. ¶¶ 441–46); Utah Antitrust Act (Count 24) (Id. ¶¶ 447–52); West Virginia Antitrust Act (Count 25) (Id. ¶¶ 453–59); and Wisconsin Antitrust Act (Count 26) (Id. ¶¶ 460–68).

[7] Specifically, Government Employees alleges violations of the: Arizona Consumer Fraud Act (Count 27) (2d Am. Compl. ¶¶ 475–83); California Unfair Competition Law (Count 28) (Id. ¶¶ 484–92); District of Columbia Consumer Protection Procedures Act (Count 29) (Id. ¶¶ 493–501); Florida Deceptive and Unfair Trade Practices Act (Count 30) (Id. ¶¶ 502–12); Illinois Consumer Fraud and Deceptive Business Practices Act (Count 31) (Id. ¶¶ 513–20); Massachusetts Consumer Protection Act (Count 32) (Id. ¶¶ 521–29); Minnesota Consumer Fraud Act (Count 33) (Id. ¶¶ 530–39); Montana Unfair Trade Practices and Consumer Protection Act (Count 34) ((Id. ¶¶ 540–44); Nebraska Consumer Protection Act (Count 35) (Id. ¶¶ 545–53); Nevada Deceptive Trade Practices Act (Count 36) (Id. ¶¶ 554–63); New Hampshire Consumer Protection Act (Count 37) (Id. ¶¶ 564–73); New Mexico Unfair Practices Act (Count 38) (Id. ¶¶ 574–83); North Carolina Unfair Trade and Business Practices Act (Count 39) (Id. ¶¶ 584–92); Oregon Unlawful Trade Practices Act (Count 40) (Id. ¶¶ 593–603); Rhode Island Deceptive Trade Practices Act (Count 41) (Id. ¶¶ 604–16); South Carolina Unfair Trade Practices Act (Count 42) (Id. ¶¶ 617–25); South Dakota Deceptive Trade Practices and Consumer Protection Law (Count 43) (Id. ¶¶ 626–35); Vermont Consumer Fraud Act (Count 44) (Id. ¶¶ 636–41); Virginia Consumer Protection Act (Count 45) (Id. ¶¶ 642–48); and West Virginia Consumer Credit and Protection Act (Count 46) (Id. ¶¶ 649–55).

The City voluntarily dismissed their claims against all Defendants on December 16, 2021. (ECF No. 101). The remaining Plaintiff, Government Employees, and Actelion engaged in a lengthy discovery process through 2023. On September 26, 2023, Government Employees filed this pending Motion for Class Certification. (ECF No. 232). Actelion filed an Opposition on December 7, 2023. (ECF No. 267). Government Employees filed a Reply on January 23, 2024. (ECF No. 275). Actelion also filed multiple Motions to Exclude the opinions and testimony of various experts relied on in Government Employees' Motion for Class Certification. (ECF Nos. 234, 237). Government Employees opposes these Motions. (ECF Nos. 262, 263). Government Employees filed a Motion and Supplemental Motion to exclude the opinions and testimony of an expert relied on in Actelion's Opposition to the Motion for Class Certification, (ECF Nos. 238, 260), which Actelion opposes, (ECF No. 265). Government Employees seeks to certify a class defined as follows:

> All entities that, for consumption by their members, employees, insureds, participants or beneficiaries, purchased, paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, in the Class States and territories[8] at any time during the period from December 29, 2015, through and until the anticompetitive effects of Defendants' challenged conduct cease.[9]

[8] The Class States and territories consist of: Arizona, California, Florida, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, the District of Columbia, and Puerto Rico.

[9] The following are excluded from the Class: (1) Defendants and their subsidiaries and affiliates; and (2) Federal and state governmental entities.

(Mot. Class Cert. at 12). Each of these proposed class-member entities is a TPP. (Id. at 7). The proposed class does not include intermediaries in the pharmaceutical payment industry such as PBMs. (See id.).

II. DISCUSSION

A. Daubert Motions

Before considering Government Employees' Motion for Class Certification, the Court must address the parties' challenges to the expert analysis underpinning their claims and defenses. In connection with their Motion for Class Certification, Government Employees moves to exclude the opinions and testimony of James W. Hughes, Ph.D, and Sean Nicholson, Ph.D, (ECF Nos. 238, 260). In connection with their Opposition to the Motion for Class Certification, Actelion moves to exclude the opinions and testimony of Laura Craft, (ECF No. 237), and Meredith Rosenthal, Ph.D, (ECF No. 234). The Court addresses the motions in turn.

1. Standard of Review

"[I]t is not yet a settled matter that a full-blown Daubert challenge should be entertained by the court when deciding a class certification motion." In re Marriott Int'l, Inc., Customer Data Sec. Breach Litig., 602 F.Supp.3d 767, 772 (D.Md. 2022). Courts in the Fourth Circuit typically conduct full Daubert analyses, especially where expert opinion is critical to the issue of class certification. 3 William B. Rubenstein, et al., Newberg on Class Actions § 7:24 (5th ed. 2021). See, e.g., Marriott, 602 F.Supp.3d at 773–74 (undertaking a full Daubert analysis where expert's testimony was essential to plaintiff's class certification motion); Childress v. JP Morgan Chase & Co., No. 16-298, 2019 WL

2865848, at * 2 (E.D.N.C., July 2, 2019) ("At the outset, the Court notes that there is no controlling precedent which dictates whether to conduct a Daubert analysis at the class certification stage or how focused or full that analysis should be . . . . The Court is persuaded by authorities which have concluded that where a movant has proffered expert testimony in support of its motion for class certification, and such testimony is critical to the issue of class certification, a full Daubert inquiry is appropriate."); Robinson v. Nationstar Mortg. LLC, No. 14-3667, 2019 WL 4261696, at *13 (D.Md. Sept. 9, 2019) ("When an expert's report or testimony is 'critical to class certification,' the district court must make a conclusive ruling on any challenge to that expert's qualifications or submissions before it may rule on a motion for class certification.") (cleaned up).

Rule 104(a) of the Federal Rules of Evidence provides that the Court "must decide any preliminary question about whether a witness is qualified . . . or evidence is admissible." This assessment includes a requirement that the Court determine admissibility of expert testimony under Rule 702. McCoy v. Biomet Orthopedics, LLC, No. ELH-12-1436, 2021 WL 252556, at *9 (D.Md. Jan. 25, 2021). The party seeking to present the expert testimony is responsible for establishing its admissibility by a preponderance of the evidence. Id.

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;

> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Under the Rule, "a properly qualified expert witness may testify regarding technical, scientific, or other specialized knowledge in a given field if the testimony would assist the trier of fact in understanding the evidence or to determine a fact in issue, and the testimony is both reliable and relevant." McCoy, 2021 WL 252556, at *10. The Court's "gatekeeping role" requires it to make determinations "of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592–93, 597 (1993)).

For evidence to be reliable, "the testimony must be grounded 'in the methods and procedures of science,' and it must be something more than subjective belief or unsupported assumptions." Id. (quoting Daubert, 579 U.S. at 590). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." Id. (quoting Belville v. Ford Motor Co., 919 F.3d 224, 232 (4th Cir. 2019)). Daubert provides the following, non-exhaustive factors for reviewing the reliability of an expert opinion:

> (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community.

Id. at *11 (citing Daubert, 509 U.S. at 593–94). The Court applies the same analysis where the expert testimony relates to matters of technical, rather than scientific, expertise. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

"Rather than provide a definitive or exhaustive list, Daubert merely illustrates the types of factors that will bear on the inquiry." United States v. Prince–Oyibo, 320 F.3d 494, 498 (4th Cir. 2003) (internal citations and quotations omitted). Daubert requires that the trial judge make a "preliminary assessment" of whether the proffered testimony is both reliable (i.e., based on "scientific knowledge") and helpful (i.e. of assistance to the trier of fact in understanding or determining a fact in issue). Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 783 (4th Cir. 1998). The Court in Daubert described the district court's gatekeeping function but reminded courts that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 596. However, this Court will not "admit opinion evidence that is connected to existing data only by the ipse dixit of the expert [where there is] simply too great an analytical gap between the data and the opinion proffered." JFJ Toys, Inc. v. Sears Holdings Corp., 237 F.Supp.3d 311, 322 (D.Md. 2017) (quoting Pugh v. Louisville Ladder, Inc., 361 F.App'x 448, 454 n.4 (4th Cir. 2010)). "Expert testimony rooted in subjective belief or unsupported speculation does not suffice." Id. (quoting Zuckerman v. Wal-Mart Stores E., LLP, 611 F.App'x 138, 138 (4th Cir. 2015)).

2. Analysis

a. James W. Hughes and Sean Nicholson

Government Employees moves to exclude two of Drs. Hughes and Nicholson's class certification opinions. (ECF Nos. 238, 260). Dr. Hughes worked as a professor of Economics at Bates College from 1992 until his retirement in 2020, and he has served as an expert in numerous pharmaceutical antitrust cases. (Hughes Rept. ¶¶ 1–2, ECF No. 267-68). Dr. Nicholson works as an economics professor at Cornell and has spent his career researching economics of the healthcare industry, with a particular focus on the pharmaceutical sector. (Nicholson Rept. ¶¶ 1–2, ECF No. 265-2). In his report, Dr. Hughes offers the opinion that because of the small patient population eligible for Tracleer or generic bosentan and the number of brand loyal consumers, a sizeable number of TPPs were uninjured by Actelion's alleged conduct in delaying generic competition. (Hughes Rept. ¶¶ 11–12). Dr. Hughes also responds to Government Employees' expert report from Dr. Rosenthal and opines that in evaluating class-wide injury and damages, she failed to account for rebates paid by Actelion to TPPs and payments from the federal government to TPPs through Medicare Part D. (Id. ¶¶ 14, 61–68, 94–95). In his report, Dr. Nicholson evaluates Dr. Rosenthal's proposed methodology for calculating damages and proposes adjusting her damages calculation to account for rebates paid to TPPs by Actelion and reimbursements paid to TPPs from the Government's Medicare Part D program. (Nicholson Sur-Rebuttal Rept. ¶¶ 4, 8, 11, ECF No. 229-2).

Government Employees first argues that Dr. Hughes' opinion that rebates and Medicare Part D payments can reduce or eliminate antitrust injury is contrary to law and

should be excluded. (Mem. Supp. Mot. Exclude Testimony of Drs. Hughes and Nicholson ["Mot. Exclude Ops. and Test. of Drs. Hughes and Nicholson"] at 9–11, ECF No 238-1). Specifically, Government Employees seeks to exclude Dr. Hughes' opinion that a TPP's receipt of manufacturer rebates negates any antitrust injury suffered by the TPP for overpayment for Tracleer or generic bosentan. (Id.). Second, Government Employees seeks to exclude Dr. Nicholson's opinion that rebates and Medicare Part D payments should be deducted from damages. (Id. at 11–15). The Court finds that Dr. Hughes' testimony is admissible in part, and Dr. Nicholson's testimony is admissible in full.

As to Dr. Hughes' opinion, several courts have rejected Dr. Hughes' argument that rebates or Medicare Part D repayments can negate antitrust injury. See In re Nexium Antitrust Litig., 777 F.3d 9, 28 n.23 (1st Cir. 2015) (rejecting Dr. Hughes's opinions regarding rebates); In re Loestrin 24 FE Antitrust Litig., 410 F.Supp.3d 352, 393 (D.R.I. 2019) (excluding in part Dr. Hughes's opinions under Rule 702). The Supreme Court has held that a plaintiff suffers antitrust injury at the moment it is overcharged due to the defendant's conduct, and "courts will not go beyond the fact of this injury to determine whether the victim of the overcharge has partially recouped . . . " Hawaii v. Standard Oil Co. of Cal., 405 U.S. 251, 262 n.14 (1972). The First Circuit has explained that "antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." Nexium, 777 F.3d at 27. In its Opposition to Government Employees' Daubert motion, Actelion conflates injury with damages and argues that some TPPs who allegedly overpaid for Tracleer were not injured because they were later reimbursed for those overcharges (something Actelion refers to as "net injury"). (Opp'n Mot. Exclude Ops. and

Test. of Drs. Hughes and Nicholson at 4–8, ECF No. 265). But courts are clear that injury and damages are distinct, and "if a class member is overcharged, there is an injury, even if that class member suffers no damages." Nexium, 777 F.3d at 27; see In re Zetia (Ezetimibe) Antitrust Litig., ["Zetia I"] No. 2:18-MD-2836, 2020 WL 5778756, at *17–18 (E.D.Va. Aug. 14, 2020) (quoting In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2017 WL 4621777, at *15 (D.Mass. Oct. 16, 2017) (agreeing with the "overwhelming weight of authority" that "later recovered damages are irrelevant to the question of impact . . . "), report and recommendation adopted, No. 2:18MD2836, 2021 WL 3704727 ["Zetia II"] (E.D.Va. Aug. 20, 2021). As such, the Court finds that Dr. Hughes opinion that rebates and reimbursements can negate antitrust injury is contrary to the law.

Federal Rule of Evidence 702(a) requires that an expert's testimony must "help the trier of fact." Opinions that are contrary to the law are unhelpful to the jury and cannot be considered scientific or reliable. See Loeffel Steel Prod., Inc. v. Delta Brands, Inc., 387 F.Supp.2d 794, 806 (N.D.Ill. 2005), amended, No. 01 C 9389, 2005 WL 8178971 (N.D.Ill. Sept. 8, 2005); Langehennig v. Sofamor, Inc., 1999 WL 1129683 at 5 n.6 (D.Kan. 1999); Bailey v. Allgas, Inc., 148 F.Supp.2d 1222, 1245–46 (N.D.Ala. 2000); Apple, Inc. v. Samsung Elecs. Co., No. 11-CV-01846-LHK, 2012 WL 2571332, at *7 (N.D.Cal. June 30, 2012); see In re Zetia (Ezitimibe) Antitrust Litig., 566 F.Supp.3d 509, 514–15 (E.D.Va. 2021). A Daubert motion is thus an appropriate mechanism to exclude expert opinions that are contrary to the law. United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, 296 F.Supp.3d 1142, 1183 (N.D.Cal.

2017). In Loestrin, a similar antitrust case against a pharmaceutical company for alleged delay of generic competition, the court excluded Dr. Hughes' opinions and testimony to the extent that he represented that a free sample offset an injury that a patient or TPP suffered. 410 F.Supp.3d at 393. Here, Dr. Hughes' opinions that rebates and Part D payments negate antitrust injury will similarly be excluded.[10]

Turning to Dr. Nicholson's opinion, the Court finds that for the purposes of class certification his testimony is admissible in its entirety. Dr. Nicholson proposes a methodology for deducting rebates and Medicare Part D cost sharing mechanisms from damages. (Nicholas Rept. ¶¶ 4, 10–11). Government Employees first argues that Dr. Nicholson's testimony should be excluded because he attempts to offer a legal opinion which does not go to a fact in dispute. (Mot. Exclude Ops. and Test. of Drs. Hughes and Nicholson at 12). The Court finds this argument unpersuasive. Dr. Nicholson offers reliable testimony grounded in facts and data. (Nicholas Rept. ¶¶ 4, 10–11). He presents a methodology for calculating damages. (Id.). This is permissible expert testimony. Government Employees also argues that Dr. Nicholson's opinions contradict the collateral source rule, under which most jurisdictions "exclude evidence of benefits received by the plaintiff from a source wholly independent of and collateral to the tortfeasor." (Mot.

[10] The Court notes that to the extent Dr. Hughes offers an opinion that rebates and Medicare Part D payments reduce or eliminate damages, that is a distinct question to antitrust injury, and his opinions will not be excluded as to damages. See In re Namenda Indirect Purchaser Antitrust Litig., 338 F.R.D. 527, 557 (S.D.N.Y. 2021) ("Setoffs that are applied later are relevant to the amount of damages a class member incurs, but a TPP that incurs an initial overcharge incurs injury, even if that injury is subsequently reduced.").

Exclude Ops. and Test. of Drs. Hughes and Nicholson at 12 (cleaned up)). The Court notes that other courts have deducted rebates or reimbursements that covered drug costs from damages calculations. See In re Namenda Indirect Purchaser Antitrust Litig., 2022 WL 3362429, at *11–12 (S.D.N.Y. Aug. 15, 2022); In re Lidoderm Antitrust Litig., 2017 WL 679367, at *25 (N.D.Cal. Feb. 21, 2017) ("If, on summary judgment or at trial, facts are shown that TPPs were reimbursed for these overcharges by the federal government . . . these can be excluded from the aggregate damages."). Whether Dr. Nicholson has calculated the measure of damages "correctly in light of the various government reimbursement programs presents a question of fact for the trier of fact – not a ruling of law for the court to make." Namenda, 2022 WL 3362429, at *12. The Court need not decide how the jury will be instructed on damages at this stage. However, Dr. Nicholson's testimony will not be excluded on the grounds of the collateral source rule at this time.

Accordingly, the Court will grant in part Government Employees' Motion to exclude the Opinions and Testimony of Dr. James W. Hughes and Dr. Sean Nicholson. (ECF Nos. 238, 260). The Court will exclude only Dr. Hughes' opinions and testimony that rebates and Medicare Part D payments negate antitrust injury. Dr. Hughes' opinions and testimony are otherwise admissible at this stage. Dr. Nicholson's opinions and testimony are at this stage admissible in full.

b. Laura Craft

Actelion filed a Motion to Exclude Laura Craft's testimony and opinions related to class certification. (ECF No. 237). Actelion argues that Craft's methodology for

ascertaining class membership is unreliable. (Mem. Supp. Mot. Exclude Ops. and Test. of Laura Craft ["Mot. Exclude Ops. and Test. of Craft"] at 5–15, ECF No. 237-1). The Court concludes that Craft is qualified to provide the opinions set forth in her report and that her proposed methodology is reliable. Craft has been the president of OnPoint Analytics, Inc. ("OnPoint"), an economic, statistical and financial consulting firm that specializes in data analytics, for twenty years. (Laura Craft Rept. ["Craft Rept."] ¶ 6, ECF No. 232-25). OnPoint devotes a significant portion of its business to commercial litigation regarding the pharmaceutical industry. (Id.). As president of OnPoint, Craft oversees the firm's work involving pharmaceutical products. To date, she has worked on sixty-five pharmaceutical cases involving antitrust allegations, including serving as an expert in eleven cases in the last four years alone. (Id. ¶ 7).

In 2017, Craft co-authored Empirical Challenges in Pharma Litigation, which describes pharmaceutical industry data sets and their analytical use in litigation. (Id.). She has also taught and developed two courses for attorneys on data analytics in the pharmaceutical industry: Data and Empirical Challenges in Pharmaceutical Litigation and Antitrust Claims Involving Pharmaceutical Products. (Id.). Craft has extensive experience in pharmaceutical data management and analysis and is well qualified to provide the opinions set forth in her report. (Id.).

Craft proposes the following methodology to identify class members and apply class exclusions. First, Craft will use pharmaceutical industry datasets maintained by intermediaries such as PBMs, datasets from the TPPs themselves, and datasets from the REMS programs to identify TPPs of Tracleer. (Id. ¶¶ 14, 27–51, 70–97). Second, Craft will

use a list of Actelion and its affiliates and subsidiaries as well as a list of federal and state government entities to exclude TPP payors who fall within one of the two class exclusions. (Id. ¶¶ 101–02, 105–07). Finally, Craft will compare the purchase data sets to claim forms submitted with affidavits to confirm which entities qualify as class members. (Id. ¶¶ 41, 99, 102, 105).

Craft concludes, based on review of available datasets, that "[t]he records created and retained in the pharmaceutical industry include highly detailed transactional data for Tracleer and bosentan" especially "given the database of information legally required as part of the REMS program that was a predicate to FDA marketing approval for these drugs." (Id. ¶ 4). Craft supports her claims as to the existence of relevant data by citing to industry regulations, and she has detailed how to use the aforementioned datasets to determine the TPPs. (Id. ¶¶ 25–26, 33–97). Contrary to Defendants' assertions, Craft need not currently have all the relevant data in order for her proposed methodology for ascertaining the class to be reliable. See Zetia II, 2021 WL 3704727, at *4 (quoting EQT Prod. Co. v Adair, 764 F.3d 347, 358 (4th Cir. 2014) ("'[P]laintiffs need not be able to identify every class member at the time of certification,' . . . so long as class members can be determined 'at some point.'"). Craft's testimony is reliable and relevant to the issue of class certification. See Daubert, 509 U.S. at 597 (expert testimony is admissible where it "both rests on a reliable foundation and is relevant to the task at hand."). Actelion may raise objections it has to Craft's testimony at trial, and the jury is entitled to choose how much weight to give to the testimony.

Numerous other courts have considered Craft's opinion in support of class certification despite the objections of defendants. See In re Namenda Indirect Purchaser Antitrust Litig., No. 115CV6549CMRWL, 2021 WL 100489, at *13 (S.D.N.Y. Jan. 12, 2021) (denying motion to exclude Craft's declaration regarding ascertainability of a proposed class); Loestrin, 410 F.Supp.3d at 400 (same); see also In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig., 335 F.R.D. 1, 24–25 (E.D.N.Y. 2020) (considering Craft's declaration as evidence in support of class certification absent a Daubert challenge); Zetia I, 2020 WL 5778756 at *8–*10 (same). The Court denies Actelion's Daubert motion as to Laura Craft.

c. Meredith Rosenthal

The Court next turns to Actelion's Motion to Exclude the Opinions and Testimony of Meredith Rosenthal, Ph.D. (ECF No. 234). Dr. Rosenthal offers an opinion on the impact of Actelion's alleged conduct and proposes a damages calculation. (Rosenthal Rept. ¶ 1, ECF No. 232-27). The Court concludes that Dr. Rosenthal is qualified to provide the opinions set forth in her report. Dr. Rosenthal is a Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. (Id. ¶ 4).

Actelion raises two challenges to Dr. Rosenthal's testimony. First, Actelion argues that her opinions are unreliable because she relies on data reflecting payments by non-class member PBMs to calculate damages and assess injury. (Mem. Supp. Mot. Exclude Test. of Dr. Rosenthal ["Mot. Exclude Ops. and Test. of Dr. Rosenthal"] at 7–9, ECF No. 234-1). Second, Actelion maintains that Dr. Rosenthal's opinions are unreliable because she

includes payments for prescriptions filled through Medicare Part D plans in assessing injury. (Id. at 9–12).

The Court finds that Dr. Rosenthal's use of the specialty pharmacy data at issue is reliable. The data Dr. Rosenthal uses to calculate damages largely comes from eight specialty pharmacies which were the exclusive distributers of Tracleer. (Rosenthal Rept. ¶ 68). Dr. Rosenthal supplements this data with two sets of REMS data produced by Actelion. (Id.). Daubert reliability "is primarily a question of the validity of the expert's methodology, not the quality of the data used . . . " Armstead v. Coloplast Corp., No. 1:19-CV-1000, 2020 WL 353576, at *2 (M.D.N.C. Jan. 21, 2020). "The soundness of the factual underpinnings of the expert's analysis . . . [is a] factual matter[] to be determined by the trier of fact." Id. (quoting Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000)). The data used by Dr. Rosenthal here is reliable, and use of similar data sets has been upheld by other courts over Daubert challenges. See In re Xyrem (Sodium Oxybate) Antitrust Litig., No. 20-MD-02966-RS, 2023 WL 3440399, at *13 (N.D.Cal. May 12, 2023).

As discussed below, the Court finds that Dr. Rosenthal's use of payments by PBMs to the specialty pharmacies to calculate damages is reliable and relevant. PBMs, acting as intermediaries for TPPs, pay the specialty pharmacies to purchase the drug on the TPPs' behalf. This price is a relevant data point in determining the amount that TPPs allegedly overpaid for Tracleer and bosentan. Actelion's objections to Dr. Rosenthal's analysis go to its weight, not its admissibility, and can be advanced at trial. See Loestrin, 410 F.Supp.3d at 394–95.

Similarly, Actelion's argument that Dr. Rosenthal's opinions and testimony should be excluded for failure to subtract Medicare Part D payments fails at this stage. Whether Dr. Rosenthal properly calculated the measure of damages "in light of the various government reimbursement programs presents a question of fact for the trier of fact – not a ruling of law for the court to make." Namenda, 2022 WL 3362429, at *12; see also Lidoderm, 2017 WL 679367, at *23 ("The jury may or may not accept the factual assumptions underlying [plaintiff expert's] analysis; at this stage, the theory is appropriate and supports certification as to the [Medicare] Part D providers.").

For purposes of the Court's determination on class certification, the Court finds that Dr. Rosenthal's analysis and methodology for assessing injury are reliable and relevant. The Court notes that other courts have regularly admitted Dr. Rosenthal's expert opinions. See In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3934597, at *6 (N.D.Ohio Aug. 20, 2019) (collecting cases); see e.g., In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., No. 17-MD-2785-DDC-TJJ, 2020 WL 1164869, at *23 (D.Kan. Mar. 10, 2020); In re Actiq Sales & Mktg. Pracs. Litig., No. A. 07-4492, 2014 WL 3572932, at *18 (E.D.Va. July 21, 2014); In re Neurontin Mktg. & Sales Pracs. Litig., 712 F.3d 21, 45 (1st Cir. 2013). Accordingly, the Court will deny Defendants' Daubert motion as to Dr. Meredith Rosenthal and will address Actelion's additional arguments as they relate to Government Employees' Motion for Class Certification below.

B. Motion for Class Certification

1. Standard of Review

Federal Rule of Civil Procedure 23(a) provides that "[o]ne or more members of a class may sue . . . as representative parties on behalf of all members only if: (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Fed.R.Civ.P. 23(a). The Fourth Circuit also reads into Rule 23 an implied requirement of "ascertainability," meaning that the Court must be able to "readily identify the class members in reference to objective criteria." Krakauer v. Dish Network, LLC, 925 F.3d 643, 654 (4th Cir. 2019) (quoting EQT Prod. Co., 764 F.3d at 358).

Additionally, "the class action must fall within one of the three categories enumerated in Rule 23(b)." EQT Prod. Co., 764 F.3d at 357 (quoting Gunnells v. Healthplan Servs., Inc., 348 F.3d 417, 423 (4th Cir. 2003)). Government Employees seeks certification under Rule 23(b)(3), which further requires that common questions of law or fact predominate over any questions only affecting individual class members and that a class action is the superior method of adjudicating the matter. Fed.R.Civ.P. 23(b)(3). The party seeking certification bears the burden of proof, and each requirement of Rule 23 must be satisfied by a preponderance of the evidence. In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 320 (3d Cir. 2008).

Class actions are an exception to the general rule that "litigation is conducted by and on behalf of the individual named parties only." Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 348 (2011). In Wal-Mart, the Supreme Court stated that "Rule 23 does not set forth a mere pleading standard. A party seeking class certification must affirmatively demonstrate his compliance with the Rule—that is, he must be prepared to prove that there are in fact sufficiently numerous parties, common issues of law or fact, etc." Id. at 350 (emphasis in original). In deciding a motion for class certification, a court must closely examine the relevant facts, even if those facts "tend to overlap with the merits of the case." Thorn v. Jefferson-Pilot Life Ins. Co., 445 F.3d 311, 319 (4th Cir. 2006). "[C]ertification is proper only if 'the trial court is satisfied, after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied.'" Wal-Mart, 564 U.S. at 350–51 (quoting Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 160 (1982)).

Courts also must conduct a "rigorous analysis" regarding disputes between experts. See In re Titanium Dioxide Antitrust Litig., 284 F.R.D. 328, 336 (D.Md. 2012). "Resolving expert disputes in order to determine whether a class certification requirement has been met is always a task for the court—no matter whether a dispute might appear to implicate the 'credibility' of one or more experts . . . " In re Hydrogen Peroxide, 552 F.3d at 324. However, "[a] court's determination that an expert's opinion is persuasive or unpersuasive on a Rule 23 requirement does not preclude a different view at the merits stage of the case." Id.

2. Analysis

a. Rule 23(a)

There is no real dispute that Government Employees' proposed class satisfies the numerosity, commonality, typicality, and adequacy requirements of Rule 23(a). The parties disagree about whether the class is ascertainable or "readily identifiable," as required by the Fourth Circuit.

i. Numerosity

The first prong of Rule 23(a) requires that the proposed class be "so numerous that joinder of all members is impracticable." Fed.R.Civ.P. 23(a)(1). While "[n]o specified number is needed to maintain a class action," Brady v. Thurston Motor Lines, 726 F.2d 136, 145 (4th Cir. 1984) (internal quotations omitted), generally, "a class of 40 or more members raises a presumption of impracticability of joinder based on numbers alone," In re Zetia (Ezetimibe) Antitrust Litig., 7 F.4th 227, 234 (4th Cir. 2021) (quoting Rubenstein et al., supra, § 3:12). This requirement is easily satisfied here, as the potential class includes at least hundreds of members. (Mot. Class Cert. at 14). Actelion does not contest that this requirement is met.

ii. Commonality

The second prong of Rule 23(a) requires that there be "questions of law or fact common to the class." Fed.R.Civ.P. 23(a)(2). "When considering commonality, the Court looks for a common contention across the class that is capable of classwide resolution." Ginwright v. Exeter Fin. Corp., 280 F.Supp.3d 674, 687 (D.Md. 2017). This analysis "goes beyond the mere presence of 'common questions of law or fact' and instead requires that

answering such questions 'will resolve an issue that is central to the validity' of each class member's claims 'in one stroke.'" Id. (quoting Wal-Mart, 564 U.S. at 350). Government Employees identifies several questions common to the class that are central to each class members' claims including, "whether Actelion had market power in the market for Tracleer and its generic equivalents" and "whether Actelion's anticompetitive scheme delayed generic entry." (Mot. Class Cert. at 15). Class-wide evidence that demonstrates Actelion dominated the relevant market or that Actelion engaged in anticompetitive conduct to delay generic entry could resolve these common questions. (Id. at 16). Actelion does not contest that this requirement, which is often met in similar antitrust cases, has been satisfied here. Accord Zetia I, 2020 WL 5778756, at *6 (collecting cases).

iii. Typicality

"To meet the typicality requirement [of Rule 23(a)(3)], a plaintiff must show that the class representative's claims and defenses are 'typical of the claims or defenses of the class.'" Ginwright, 280 F.Supp.3d at 686 (quoting Fed.R.Civ.P. 23(a)(3)). "That is, 'the named plaintiff's claim and the class claims [must be] so interrelated that the interests of the class members will be fairly and adequately protected in their absence.'" Deiter v. Microsoft Corp., 436 F.3d 461, 466 (4th Cir. 2006) (quoting Gen. Tel. Co., 457 U.S. at 155). "The premise of the typicality requirement is simply stated: as goes the claim of the named plaintiff, so go the claims of the class." Broussard v. Meineke Discount Muffler Shops, 155 F.3d 331, 340 (4th Cir. 1998) (quoting Sprague v. General Motors Corp., 133 F.3d 388, 399 (6th Cir. 1998)). Here, Government Employees' claims are typical of the class. Government Employees' claims and the rest of the class members' claims arise from

the same legal theory and the same allegedly unlawful conduct by Actelion. (Mot. Class Cert. at 17). Actelion also does not argue that this requirement is not met.

iv. Adequacy

Rule 23 requires that the named plaintiff "fairly and adequately protect the interests of the class." Fed.R.Civ.P.23(a)(4). "The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent. A class representative must be part of the class and possess the same interest and suffer the same injury as the class members." Amchem Prod., Inc. v. Windsor, 521 U.S. 591, 625–26 (1997) (cleaned up). Here, Government Employees has the same interest in establishing liability as the proposed class, and it suffered the same alleged injury as the proposed class. Government Employees, and the rest of the class, all allege that they overpaid for Tracleer and generic bosentan because of Actelion's allegedly anticompetitive conduct. (Mot. Class Cert. at 11–12). Government Employees is well qualified and is an adequate representative for the absent class members. Actelion does not argue otherwise.

v. Ascertainability

In addition to Rule 23(a)'s threshold requirements, the Fourth Circuit also recognizes that "Rule 23 contains an implicit threshold requirement that the members of a proposed class be 'readily identifiable,'" which has also been named an "ascertainability" requirement. EQT Prod. Co., 764 F.3d at 358 (quoting Hammond v. Powell, 462 F.2d 1053, 1055 (4th Cir. 1972)). To be ascertainable, the class must be identifiable based on "objective criteria," such that it would be "administratively feasible for the court to determine whether a particular individual is a member." Id. (quoting 7A Charles Alan

Wright et al., Federal Practice & Procedure § 1760 (3d ed. 2005)). A class will not be certified where "class members are impossible to identify without extensive and individualized fact-finding or mini-trials." EQT Prod. Co., 764 F.3d at 358 (internal citations and quotations omitted). However, "[p]laintiffs need not be able to identify every class member at the time of certification." Id.

Government Employees asserts that under their proposed class definition, class members can be identified based on objective criteria by using a combination of data sets and claim affidavits. (Mot. Class Cert. at 18–23). Actelion argues that Government Employees' proposed methodologies do not present an administratively feasible way for the Court to distinguish between the final TPPs, which are potential class members, and non-class member intermediaries and non-payors including PBMs, third-party administrators, and administrative service only providers, as well as government entities. (Mem. Opp'n Pls.' Mot. Class Cert. ["Opp'n Class Cert."] at 15, ECF No. 267).

Here, the class is precisely defined based on "objective criteria." Members of the class must meet five requirements. They must have: "(i) purchased, paid, and/or reimbursed some or all of the purchase price of Tracleer or generic bosentan, other than for resale, (ii) for consumption by their members, employees, insureds, participants, or beneficiaries (iii) in a discrete set of states, (iv) on or after December 29, 2015, and (v) do not fall within either of the exclusions." (Mot. Class Cert. at 19). As explained above, Government Employees' expert Laura Craft opines that, using a combination of detailed pharmaceutical data sets and affidavits contained in claims forms, she can identify who satisfies this criteria

and apply the relevant exclusions. Actelion does not dispute that the class is identifiable based on objective criteria.

The parties extensively dispute whether determining the class is "administratively feasible." Government Employees' expert, Craft, opines that there is an administratively feasible method to determine the class members based on these criteria. Craft states that "[p]rescription drugs are likely the most heavily documented purchase transactions for any consumer good in the United States," and there is a "vast collection of detailed transaction records which . . . can be used to confirm members of the class and apply the specified exclusions." (Craft Rept. ¶ 15). Federal regulations require detailed information to be kept regarding each drug purchase, which includes the individual consumer and the TPP (the potential class member). This data is housed by the PBM, the TPP, the pharmacy that dispenses the drug, and the REMS administrator. Here, the relevant data is housed by the "approximately ten specialty, mail-order pharmacies" which exclusively dispensed Tracleer from December 2015 to June 2019 as well as seven PBMs "which cover more than 89 to 96 percent of all transactions" relevant here.[11] (Mot. Class Cert. at 21 n.11). Craft asserts that the data available to confirm class membership in this case is especially extensive because Tracleer and generic bosentan are subject to a REMS program, and the REMS administrator also holds data sets which can be used to confirm class membership. (Craft Rept. ¶¶ 17, 52–59). According to Craft, the various pharmaceutical purchase data

[11] The four largest, CVS Caremark, Express Scripts, OptumRx, and Humana, have already produced data in this matter which can be used to identify class members.

sets jointly contain the criteria necessary to determine class membership and exclusions. (Id. ¶¶ 33, 14, 21, 26, 36, 50).

Actelion relies extensively on Third Circuit caselaw to argue that the class is not ascertainable. (Opp'n Class Cert. at 19). Though the Fourth Circuit used the phrase "administratively feasible," it has never explicitly adopted Third Circuit's ascertainably standard, which is considered by many to be an outlier. See Mullins v. Direct Digit., LLC, 795 F.3d 654, 662 (7th Cir. 2015); 7A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1760 (4th ed. 2024); 6 William B. Rubenstein, Newberg and Rubenstein on Class Actions § 20:33 (6th ed. 2024). However, the Court need not determine which approach to apply here. Even if the Court were to apply the Third Circuit's stricter approach, the proposed class meets the requirements of ascertainably. "[T]he case law 'does not suggest that no level of inquiry as to the identity of class members can ever be undertaken.'" Marriott Int'l, Inc., Customer Data Sec. Breach Litig., 341 F.R.D. 128, 144 (D.Md. 2022) (quoting Byrd v. Aaron's Inc., 784 F.3d 154, 171 (3d Cir. 2015)), vacated and remanded sub nom., 78 F.4th 677 (4th Cir. 2023), and reinstated, 345 F.R.D. 137 (D.Md. 2023).

Actelion relies on the Third Circuit's opinion in Niaspan to show that the proposed class here is not ascertainable, (Opp'n Class Cert. at 19), but that case is factually distinguishable. As the Eastern District of Virginia explained in Zetia, "the proposed class in Niaspan included TPPs and consumers," and the court's ascertainability determination in Niaspan "hinged, in large part, on its finding that the plaintiffs had failed to provide sufficient evidence that they could identify and exclude from the consumer subclass certain

uninjured consumers." 2020 WL 5778756, at *11. Here, as in Zetia, the proposed class contains only TPPs, and the issues the Niaspan Court identified with respect to excluding unharmed consumers are not present. Additionally, while in Niaspan the methodology for determining class members relied solely on PBM records, here the methodology relies on multiple data sources, including TPPs' own records, which can be verified by claims forms. See 67 F.4th 118, 125, 135–36 (3d Cir. 2023); (Mot. Class Cert at 13). Finally, while the court in Niaspan concluded that plaintiffs had identified no methodology to exclude federal and state governmental entities, here Craft has identified a methodology for excluding government entities through PBM data and claims administration. (Craft Rept. ¶¶ 100–105).

Actelion also cites to Third Circuit caselaw to show that Craft's proposed use of claims forms to supplement the pharmaceutical data is too individualized to be considered administratively feasible. (Opp'n Class Cert. at 22). But even the Third Circuit has held, "a straightforward 'yes-or-no' review of existing records to identify class members is administratively feasible even if it requires review of individual records with cross-referencing of voluminous data from multiple sources." Kelly v. RealPage, Inc., 47 F.4th 202, 224 (3d Cir. 2022). Though reviewing claims forms requires additional analysis, "the number of 'steps' in the process and the time and effort required have no bearing on whether the class is ascertainable." Zetia I, 2020 WL 5778756, at *14 (quoting Soutter v. Equifax Info. Servs. LLC, 307 F.R.D. 183, 197 (E.D.Va. 2015)).

Courts have found that similar classes to the proposed class here are ascertainable and have approved similar methods to determine class membership to those proposed by

Government Employees and Craft. See e.g., Zetia I, 2020 WL 5778756, at *14; Namenda, 338 F.R.D. at 550; In re Opana ER Antitrust Litig., 2021 WL 3627733 (N.D.Ill. June 4, 2021), as amended, Case No. 14-cv-10150, ECF No. 746 (N.D.Ill. Aug. 11, 2021); Soutter, 307 F.R.D. at 196–97 (certifying class and allowing "some degree of manual review" to determine class membership where "the majority of sifting in this case will be achieved through dataset searches"). "The plaintiffs need not be able to identify every class member at the time of certification." EQT Prod. Co., 764 F.3d at 358. At this stage, Government Employees has satisfied its burden of showing the proposed class is ascertainable.

b. Rule 23(b)

In addition to the Rule 23(a) requirements, plaintiffs must demonstrate that the class action fits within one of the provisions of Rule 23(b). Government Employees asserts that the proposed class here should be certified under Rule 23(b)(3). (Mot. Class Cert. at 23–33). Under this provision, class certification is appropriate if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed.R.Civ.P. 23(b)(3).

i. Predominance

While similar to Rule 23(a)'s commonality requirement, the test for predominance under Rule 23(b)(3) is "far more demanding" and "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." Amchem, 521 U.S. at 623–24. Plaintiffs "are not required to prove that each element of their claims is susceptible to classwide proof, but only that common questions predominate over any questions

affecting only individual [class] members." Zetia I, 2020 WL 5778756, at *14 (cleaned up). And "any model supporting a 'plaintiffs[']damages case must be consistent with its liability case.'" In re Marriott, 341 F.R.D. at 161 (quoting Comcast, 569 U.S. at 35). "Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws." Amchem, 521 U.S. at 625.

Here, Actelion does not contest that Government Employees can show predominance with respect to liability. "Indeed, allegations of antitrust-violative conduct tend to focus on the defendants' conduct rather than evidence specific to individual class members and thus can be proven using evidence common to the class." Zetia I, 2020 WL 5778756, at *15. Government Employees puts forward evidence common to the class to support liability and damages including "(i) evidence of the impact of . . . FDA regulations on market conditions; (ii) evidence of the effects of generic competition on prices; (iii) transactional data of actual prices and quantities of brand and generic Tracleer; and (iv) the competitive price and quantities sold for brand and generic Tracleer absent [Actelion's] unlawful conduct." (Mot. Class Cert. at 31). Actelion raises two challenges to predominance: the presence of uninjured class members and the ability to measure damages on a class-wide basis. (Opp'n Class Cert. at 26–35). The Court addresses each argument in turn.

A. Injury

Actelion argues that Government Employees' putative class cannot meet its predominance burden because it includes a significant number of uninjured class members,

and identifying the class members will require individualized inquiries that predominate over common questions. (Opp'n Class Cert. at 26).

"The Fourth Circuit has not yet defined a precise standard for determining what number or proportion of uninjured class members would defeat certification." Zetia I, 2020 WL 5778756, at *15. The relevant question is "whether the differences among the class members are so great that individual adjudication subsumes the class-wide issues." Krakauer, 925 F.3d at 657. "The entire notion of predominance implies that the plaintiffs' claims need not be identical, and, as the Supreme Court has noted, a class can meet this requirement 'even though other important matters will have to be tried separately.'" Id. at 658 (quoting Tyson Foods, Inc. v. Bouaphakeo, 577 U.S. 442, 453–54 (2016)).

Here, Government Employees alleges that class member TPPs were injured because they were overcharged for both Tracleer and generic bosentan as a result of Actelion's delay of generic competition. (Mot. Class Cert. at 28). Actelion disputes class-wide injury, arguing that a number of TPPs' members were uninjured because they were "brand loyal" and continued to purchase the brand-name Tracleer even after the generic bosentan became available. (Opp'n Class Cert. at 26). According to Actelion, "[b]ecause the patient never switches to the generic, they do not incur an overcharge and neither do the TPPs that cover their prescription costs." (Id.).

This argument fails to defeat class certification. As Government Employees argues, the price of brand-name Tracleer may have been lower had the generic version entered the market earlier and created competition thus driving the price of even the brand-name bosentan down. (Mot. Class Cert. at 28; Pls.' Reply Supp. Class Cert. ["Reply"] at 14–16,

ECF No. 275). This is known as "brand-brand" injury and is widely accepted by courts. See In re Ranbaxy Generic Drug Appl. Antitrust Litig., 573 F.Supp.3d 459, 472 (D.Mass. 2021) (collecting cases). Dr. Rosenthal provides evidence common to the class that Actelion regularly increased the price of Tracleer and caused TPPs to pay more for brand-name bosentan for a longer period of time by delaying generic entry. (Rosenthal Rept. ¶¶ 12–13 & Fig. 1).

Even if the Court assumes that a significant number of brand loyal consumer purchasers who only would have purchased brand-name Tracleer exist, the TPPs who covered the costs of those brand-loyal purchases still may have overpaid for the brand-name Tracleer and suffered injury. While some courts have determined that brand-loyal end consumer payors could present an obstacle to class certification, see e.g., In re Niaspan Antitrust Litig., 464 F.Supp.3d 678, 717 (E.D.Pa. 2020), Actelion does not identify, and the Court is not aware of, any case where TPPs were considered uninjured because of brand-loyal members. In fact, "[c]ourts facing the issue of brand-loyal TPPs have universally concluded that it is 'highly unlikely' that 'institutional payors were uninjured even if some of their members are brand-loyal.'" Zetia I, 2020 WL 5778756, at *19 (quoting Loestrin, 410 F.Supp.3d at 402).

Under a brand-brand injury theory, virtually all TPP class members are injured. Even if the court were to consider a brand-loyal injury theory, the number of uninjured TPPs is de minimus. Actelion posits that the rate of brand loyal consumer payors was 14% or 17–19%. (Opp'n Class Cert. at 29). However, the relevant number here is the number of uninjured TPPs, not consumer payors. Actelion does not provide an estimate for the

percentage of uninjured TPPs across the class. Government Employees estimates that under 8% of TPPs are uninjured based on a brand-loyalty theory, which is below the percentage other circuits have found defeats certification. See In re Asacol Antitrust Litig., 907 F.3d 42, 53–54 (1st Cir. 2018) (overturning the certification of class where about 10% of class members were uninjured); In re Rail Freight Fuel Surcharge Antitrust Litig., 934 F.3d 619, 624–25 (D.C. Cir. 2019) (affirming denial of class certification where about 12.7% of class members were uninjured); (Reply at 17). PAH is a rare condition, which is estimated to affect 3,750 to 15,000 adults. (Opp'n Class Cert. at 28). As a result, many TPPs (here an estimated 60%) only have one member who is prescribed bosentan. (Id. at 29). Still, a TPP needs only one single qualifying purchase to qualify as a class member. Zetia I, 2020 WL 5778756, at *18.

The number of TPPs that had only members who purchased brand Tracleer even after the generic version became available is extremely small, and Dr. Rosenthal has demonstrated that she could exclude them if they are found to have suffered no injury. (Rosenthal Rept. ¶¶ 82–83); see In re Niaspan, 464 F.Supp.3d at 717 ("[When] there are a substantial number of brand loyalists in the class . . . , [plaintiffs] have the burden of showing that excluding them can be accomplished without extensive individualized inquiry."). Additionally, as courts within this Circuit have previously found, "evidence that certain purchasers within any TPP would have remained loyal to the brand may be addressed during trial without resorting to individualized inquiry or overwhelming common issues." Zetia I, 2020 WL 5778756, at *19.

Actelion raises several purported flaws with Dr. Rosenthal's analysis. First, Actelion argues that Dr. Rosenthal's analysis is unduly individualized. (Opp'n Class Cert. at 30–31). However, as Actelion admits, Dr. Rosenthal's report is based on an "'[a]ggregate [p]ayment [a]nalysis' on a class-wide basis." (Id. at 31). "'[T]he need for some individualized determinations' is not fatal to class certification." Zetia I, 2020 WL 5778756, at *23 (quoting Nexium, 777 F.3d at 21.). Second, Actelion argues that Dr. Rosenthal failed to account for rebating. (Opp'n Class Cert. at 31–34). However, while rebates may be relevant to the question of damages, as the Court explained above, they are "simply irrelevant to the question of antitrust injury." Xyrem, 2023 WL 3440399, at *9. This is because "antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." Nexium, 777 F.3d at 27. Even if some of a TPPs' payments were later covered by Medicare Part D or other rebates, "the alleged overcharge would still have occurred — and that is all that need be shown on a classwide basis." Xyrem, 2023 WL 3440399, at *9.

Actelion's expert, Dr. Hughes also identifies several more specific flaws including that (i) "Dr. Rosenthal inappropriately compares PBM payments associated with specific patients across different TPPs;" (ii) "Dr. Rosenthal utilizes the incorrect pre-generic entry benchmark period;" and (iii) "Dr. Rosenthal selectively picks the last prescription before generic entry." (Opp'n Class Cert. at 31). These purported flaws do not defeat class certification. As explained above, even TPPs who would not have paid for generic bosentan after generic entry were injured on a brand-brand theory. To the extent Dr. Hughes and Dr. Rosenthal's opinions differ, Dr. Rosenthal has adequately rebutted Dr. Hughes opinions at

this stage. (See Rosenthal Rebuttal Rept. at 10–11, ECF No. 260-12); see also Zetia I, 2020 WL 5778756, at *18. These arguments can be re-raised in cross-examination at trial.

The Court finds that Government Employees has sufficiently shown that a plausible methodology to demonstrate antitrust injury can be proven on a class-wide basis using common proof.

B. Damages

Government Employees must also show that "damages can be reliably measured on a class-wide basis" using a methodology that is consistent with the theory of liability. Zetia I, 2020 WL 5778756, at *23 (quoting Am. Sales Co., LLC v. Pfizer, Inc., No. 2:14361, 2017 WL 3669604, at *15 (E.D.Va. July 28, 2017), report and recommendation adopted, No. 2:14361, 2017 WL 3669097 (E.D.Va. Aug. 24, 2017)). At this stage, plaintiffs are "not required to prove damages by calculating specific damages figures for each member of the class, but rather they must show that a reliable method is available to prove damages on a class-wide basis." Id. (quoting In re Wellbutrin XL Antitrust Litig., 282 F.R.D. 126, 144 (E.D.Pa. 2011)). "[A]ntitrust plaintiffs have a limited burden with respect to showing that individual damages issues do not predominate." Id. at *24 (quoting In re Cardizem CD Antitrust Litig., 200 F.R.D. 326, 348 (E.D.Mich. 2001)).

Government Employees puts forward Dr. Rosenthal's methodology to support class-wide damages. (Mot. Class Cert. at 30–31). To calculate damages, Dr. Rosenthal uses a "yardstick approach," which is a commonly used model in antitrust cases. (Rosenthal Rept. ¶ 51); see In re Flonase Antitrust Litig., 284 F.R.D. 207, 232 (E.D.Pa. 2012) (approving the yardstick methodology and stating that the "'yardstick' methodology has

been accepted by courts as a means to measuring damages in both indirect and direct purchaser antitrust actions"); Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 175 F.3d 18, 24 n.3 (1st Cir. 1999) (noting that the "yardstick method" is an "accepted method[] of economic analysis"); Restasis, 335 F.R.D. at 18 (stating that the yardstick approach is a "generally accepted way to measure antitrust damages"). Under the yardstick model, Dr. Rosenthal uses data from the actual entry of generic bosentan to create a yardstick to estimate the price of brand-name and generic bosentan had the generic bosentan been available at a given date. (Rosenthal Rept. ¶¶ 51, 59–66). Using this estimated price, Dr. Rosenthal calculates the difference between the amount TPPs actually paid for generic and brand-name bosentan and they amount they would have paid had generic bosentan been available at the time. Dr. Rosenthal multiplies this overcharge amount by the total quantity purchased to determine the total damages for the TPP class. (Id. ¶ 57). To calculate prices and quantities of brand and generic bosentan, Dr. Rosenthal uses claims data from specialty pharmacies that were the exclusive distributors of Tracleer and data from REMS prescription tracking. (Id. ¶ 68). This data tracks transactions between the pharmacies and PBMs. (Id.).

Actelion argues that Government Employees' damages model does not sufficiently show proof of damages on a class-wide basis. (Opp'n Class Cert. at 34). Specifically, Actelion claims that Dr. Rosenthal's damages model, which utilizes data from specialty pharmacies that track transactions from non-plaintiff PBMs to calculate payments made by TPPs, does not adequately show injury as to the class members. (Id. at 34–35). Actelion posits that the payment a PBM remits to a pharmacy can differ from the amount a TPP

pays to a PBM, but Actelion does not provide any evidence of this occurring here. (Id.). Regardless, this difference does not preclude class certification. The role of PBMs is, as Actelion explains, to act as "intermediaries" and pay pharmacies on TPPs behalf. (Id. at 11); see also Restasis, 335 F.R.D. at 30 ("PBMs are not end-payors"). The price that PBMs paid specialty pharmacies for brand and generic bosentan then is highly relevant, if not conclusive, for calculating the damages suffered by the proposed class.

"Given the inherent difficulty of identifying a 'but-for world,'" antitrust damages need not "be measured with certainty." Behrend v. Comcast Corp., 655 F.3d 182, 203 (3d Cir. 2011) (citations omitted), rev'd on other grounds, 569 U.S. 27 (2013). Antitrust plaintiffs need only "show that a reliable method is available to prove damages on a class-wide basis." Wellbutrin XL, 282 F.R.D. at 144. The Court is satisfied that the damages methodology proposed by Dr. Rosenthal is sufficiently reliable to meet the class certification requirements here and is consistent with Government Employees' purported theory of liability. Government Employees here has met its "limited burden" at this stage. Zetia I, 2020 WL 5778756, at *24; see also New York v. Julius Nasso Concrete Corp., 202 F.3d 82, 88–89 (2d Cir. 2000). Additionally, Dr. Rosenthal's damages model is directly tied to Government Employees' liability theory that Actelion's anticompetitive conduct delayed generic entry, thus resulting in overcharges to TPP class members. The Court finds that Government Employees has demonstrated a reliable method of calculating class-wide damages for purposes of class certification and that common issues predominate over individual issues with respect to class-wide damages calculations.

ii. Superiority

Finally, Government Employees must demonstrate "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed.R.Civ.P. 23(b)(3). To determine whether a class action is the superior method to resolve this dispute, the court "must compare the possible alternatives to determine whether Rule 23 is sufficiently effective to justify the expenditure of the judicial time and energy that is necessary to adjudicate a class action and to assume the risk of prejudice to the rights of those who are not directly before the court." Stillmock v. Weis Markets, Inc., 385 F.App'x 267, 274 (4th Cir. 2010) (quoting Wright et al., supra, § 1779). The superiority requirement ensures that resolution of claims by class action will "'achieve economies of time, effort, and expense, and promote . . . uniformity of decision without sacrificing procedural fairness or bringing about other undesirable results.'" Amchem, 521 U.S. at 615 (quoting Fed.R.Civ.P. 23 advisory committee's note to 1966 class-action amendments).

Actelion does not contest that the superiority requirement is met here. The Court finds that interests of efficiency and preservation of judicial resources as well as the consistency of results support the superiority of class adjudication here. See Zetia I, 2020 WL 5778756, at *28. Indeed, the "vast majority of district courts" in "delayed generic entry case[s]" conclude that "class action treatment is superior to other available methods of adjudication." Flonase, 284 F.R.D. at 234. Accordingly, the Court finds that the superiority requirement is met.

c. Rule 23(g)

Lastly, Government Employees seeks to appoint Sharon K. Robertson of Cohen Milstein Sellers & Toll PLLC and Thomas M. Sobol of Hagens Berman Sobol Shapiro

LLC as co-lead class counsel. The Court previously appointed Robertson and Sobol as Interim Lead Class Counsel finding that they and their respective firms possessed "extensive experience with and expertise in pharmaceutical class actions and their work to date in developing the claims" in this case. (See Jan. 18, 2019 Order Consolidating Cases and Appointing Interim Lead Class Counsel at 2, ECF No. 33). For those same reasons, as well as counsels' diligent litigation of the case thus far, the Court confirms Sharon K. Robertson of Cohen Milstein Sellers & Toll PLLC and Thomas M. Sobol of Hagens Berman Sobol Shapiro LLC as co-lead class counsel.

III. CONCLUSION

For the foregoing reasons, the Court will grant Government Employees' Motion to Certify Class (ECF No. 232). The Court will grant in part and deny in part Government Employees' Motion to Exclude the Opinions of James W. Hughes, Ph.D and Sean Nicholson, Ph.D Related to Class Certification (ECF Nos. 238, 260). The Court will deny Actelion's Motion to Exclude the Opinions and Testimony of Meredith Rosenthal, Ph.D (ECF Nos. 234, 245), and the Court will deny Actelion's Motion to Exclude the Opinions and Testimony of Laura Craft (ECF Nos. 237, 246). A separate Order follows.

Entered this 6th day of September, 2024.

/s/
George L. Russell, III
Chief United States District Judge